EDITOR'S CHOICE

Passive Mobilization With Place-and-Hold Versus Active Mobilization Therapy After Flexor Tendon Repair: 5-Year Minimum Follow-Up of a Randomized Controlled Trial

Sara Chevalley, MD, MSc,*† Victoria Wängberg, MD,*† Martina Åhlén, MD, PhD,† Joakim Strömberg, MD, PhD,†‡ Anders Björkman, MD, PhD*†

Purpose There is no consensus on the optimal postoperative rehabilitation program following flexor tendon repair. Some studies suggest a faster recovery after active mobilization, whereas other studies have failed to find any differences between active and passive mobilization at 12 months. To our knowledge, no prior randomized controlled trial has compared the long-term effects of these two approaches. This randomized controlled trial compared the long-term outcomes of active mobilization with those of passive mobilization in combination with place-and-hold.

Methods Sixty-four patients with a flexor tendon injury in zones I or II were included in the study. After surgery, patients were randomized to either active mobilization or passive mobilization with place-and-hold. Forty-seven patients were available for the 5-year minimum follow-up. Assessments included range of motion, grip strength, key pinch, as well as the Disabilities of the Arm, Shoulder, and Hand (DASH) and ABILHAND questionnaires.

Results At the 5-year minimum follow-up, range of motion was significantly better in the group treated with passive mobilization with place-and-hold compared with the active mobilization group. Furthermore, there was a significant deterioration in the range of motion and an increased flexion contracture in the active mobilization group compared with 1 year after surgery. Grip strength deteriorated significantly in both groups from the 1-year to the 5-year minimum follow-up, but key pinch did not change. In both groups, DASH and ABILHAND scores improved from the 1-year to the 5-year minimum follow-up.

Conclusions Passive mobilization with place-and-hold following flexor tendon repair results in superior long-term outcomes compared with active mobilization. *(J Hand Surg Am. 2024;■(■):■−■.*

Type of study/level of evidence Therapeutic I.

Key words Early active mobilization, flexor tendon repair, long-term follow-up, passive mobilization, zones I and II.

THE STATE-OF-THE-ART TREATMENT of flexor tendon injuries in the hand is primary repair with multistrand core sutures and epitendinous sutures strong enough to permit early mobilization.[1−3] The goal of postoperative motion programs following flexor tendon repair is to prevent

*From the *Department of Hand Surgery, Sahlgrenska University Hospital, Mölndal, Sweden; the †Department of Hand Surgery, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; and the ‡Department of Surgery and Orthopaedics, Alingsås Hospital, Alingsås, Sweden.*

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Corresponding author: Sara Chevalley, MD, MSc, Department of Hand Surgery, Sahlgrenska University Hospital, SE-431 80 Mölndal, Sweden; e-mail: sara.chevalley@gu.se.

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or disrupt adhesions that restrict tendon motion and to prevent joint stiffness, both of which are imperative for recovery of the active range of finger motion. However, there is no consensus on which postoperative rehabilitation program gives the best range of motion (ROM), grip strength, and patient-reported outcomes following flexor tendon repair. Some studies have suggested that active mobilization is better than passive mobilization.[4,5] However, others have not found any significant differences in ROM or grip strength, and one study has reported better ROM after modified Kleinert/Duran passive mobilization with place-and-hold compared with active mobilization.[6–9] In addition, the terminology used in the literature for describing different rehabilitation strategies is confusing.[5] A recent Cochrane systematic review concluded that there is a lack of evidence for early passive mobilization with place-and-hold as well as true active mobilization following flexor tendon repair.[10] In addition, the authors noted that most studies on these interventions were case series reporting only objective measurements and seldomly included patient-reported outcome measures.[10] Furthermore, few studies, none of which are randomized clinical trials (RCTs), have investigated how the choice of rehabilitation strategy affects ROM, grip strength, and patient-reported outcomes more than 1 year after surgery.[11,12]

Most postoperative rehabilitation protocols for flexor tendon injuries include exercises up to 12 weeks after the injury, whereafter restrictions are lifted and supervised therapy is discontinued.[13] After this time, patients are frequently recommended to continue to practice joint movement and be observant about activities performed with the injured hand. However, for many hand disorders, when formal rehabilitation stops, patients can lose gains in function achieved during rehabilitation, that is, ROM, and function can decrease over time.[13] Flexor tendon healing is known to be a lengthy process involving the healing of the tendon and surrounding tissues and the re-establishment of several gliding surfaces. Thus, studies with long-term follow-up are crucial when assessing outcomes following flexor tendon repair.

The aim of this RCT was to investigate objective as well as patient-reported outcomes following active mobilization compared with passive mobilization with place-and-hold at a minimum of 5 years after flexor tendon repair in zones I and II.

METHODS

Study design and patient enrolment

This is a 5-year minimum follow-up of an RCT previously reported by Chevalley et al.[6] The detailed study design has been published along with the 1-year results.[6] Briefly, patients admitted to the Department of Hand Surgery, Sahlgrenska University Hospital, with a flexor tendon injury between 2013 and 2017 were screened for inclusion in the study. Inclusion criteria were complete transection of the flexor digitorum profundus tendon 2−5 in zones I or II, age over 16 years, and the ability to go through with early mobilization. Patients who had a concomitant injury to the flexor digitorum superficialis (FDS) tendon and/or a digital nerve injury were accepted for inclusion if the other criteria were met. Exclusion criteria were concomitant severe injuries, such as fractures or soft tissue defects, distal injuries in zone I that required reinsertion of the tendon to the bone, impaired hand function from previous injuries, inability to follow an early mobilization protocol, active drug abuse, and psychiatric disorders.

A total of 64 patients were randomized to either active mobilization or passive mobilization with place-and-hold, and 55 patients were examined at the 1-year follow-up.[6] The long-term follow-up was conducted at a minimum of 5 years after surgery. The patients were examined between November 2021 and January 2023 by a hand surgeon who had not participated in their treatment and who was blinded to the mobilization protocol the patient followed.

All patients in this study received verbal and written information about the trial before giving written informed consent to participate. The trial was approved by the Swedish ethics review authority, regional ethics committee in Gothenburg, Sweden, before conducting the study, and carried out in accordance with the Declaration of Helsinki. The Consolidated Standards of Reporting Trials guidelines were followed, and the trial was registered at the website ClinicalTrials.gov PRS (Protocol Registration and Result System), https://clinicaltrials.gov. ClinicalTrial.gov Identifier: NCT04385485, protocol ID 1001.

Outcome measurements

The primary outcome, ROM, was measured using a goniometer and calculated as the total flexion in the proximal interphalangeal (PIP) and distal interphalangeal (DIP) joints minus a flexion contraction, if present. A flexion contraction was defined as the angle, measured in degrees, from full extension in the PIP and DIP joints when there was an extension lag in any of those joints. Range of motion was also categorized according to Strickland and Glogovac[14]

as excellent, good, fair, and poor based on the Strickland formula:

$$\left(\frac{\textit{Active PIP} + \textit{DIP flexion} - \textit{extension lag}}{175} \times 100 = \textit{\% of normal active PIP and DIP motion}\right).$$

Grip strength was measured using a Jamar dynamometer (Sammons Preston), and the lateral (key) pinch was measured with a hydraulic pinch gauge (Sammons Preston). The same dynamometer and pinch gauge were used for all measurements. Patient-reported outcomes were assessed using the validated Swedish versions of the Disabilities of the Arm, Shoulder, and Hand (DASH) and ABILHAND questionnaires.[15–18] Grip strength, key pinch, DASH, and ABILHAND questionnaires were secondary outcomes.

Surgical technique

All operations were performed in the same way with a four-stranded core suture and an epitendinous suture by specialists in hand surgery or senior residents in hand surgery. The flexor digitorum profundus tendon was repaired with two modified Kessler sutures, that is, a four-strand end-to-end core suture with a 4−0 nonabsorbable braided polyester suture (Ti-Cron, Medtronic) and a running epitendinous suture according to Silfverskiöld and Andersson[19] using 6−0 nonabsorbable monofil polypropylene (Prolene, Ethicon). Any concomitant injury of the FDS tendon was repaired according to the surgeon's preference. We find the four-stranded core suture in combination with the epitendinous suture according to Silfverskiöld and Andersson[19] strong enough for early mobilization without excessive bulkiness that could negatively affect rehabilitation. Injured digital nerves were repaired with an 8−0 or 9−0 nonabsorbable polyamide monofilament (S&T AG).

Rehabilitation

One to 3 days after surgery, the patients were randomized to either active mobilization or passive mobilization with rubber bands and place-and-hold by a hand therapist (HT) at the hand rehabilitation unit. The patients in both groups had follow-up visits with an HT regularly for 12 weeks. At each visit, the therapist assessed compliance with the rehabilitation program by asking if the patient had performed fewer, the correct number, or more training sessions and repetitions than recommended since the last visit. In addition, patients were assessed by the same HT at 6 and 12 months after surgery. Patients in both groups were allowed to perform normal activities after 12 weeks and heavy manual work and gym training after 4 months. Both rehabilitation programs include the so-called place-and-hold, which means the patient performs a gentle squeeze with the fingers after they have been passively flexed.[13] The main difference between the two programs is whether they allow active finger flexion or limit patients to passive finger flexion during the first 4 weeks following surgery.

Active mobilization: The active mobilization program was based on a modification of the programs described by Small et al[20] and Elliot et al.[21] On the first day of mobilization, a dorsal splint was made for the patient with the wrist in a neutral position and the metacarpophalangeal joints in 60−80 degrees of flexion. In addition, a removable volar plate, which kept the fingers extended, was used between the hand therapy sessions. The patients were instructed to flex their fingers passively with the uninjured hand, one at a time, and then to keep the fingers in flexion and perform a gentle squeeze, the so-called place-and-hold, for 3 seconds. The fingers were then extended actively as far as the splint allowed. This motion was performed with five repetitions, 10 times a day, with a 1.5-hour resting period between sessions. In every second training session, all the fingers were flexed actively three times. After a week, the exercise was performed with 10 repetitions, 10 times a day, with a resting period of 1.5 hours between training sessions. Four weeks postsurgery, the splint was removed and replaced by a removable wrist lacer with the wrist in a neutral position. Flexion and extension of the wrist were added with 10 repetitions, 4 times a day, and individual training for the joints in the injured finger with three repetitions 10 times a day, in addition to the previous protocol. Six weeks postsurgery, the wrist lacer was removed, and the same exercise was continued until 12 weeks after surgery.

Passive mobilization with place-and-hold: The program for passive mobilization with place-and-hold was similar to that described by Silfverskiöld and May.[22] Before mobilization, the patients received a dorsal forearm plaster ending at the level of the PIP joints, with the wrist in a neutral position and a dorsal block over the proximal phalanges, creating an extension block for the metacarpophalangeal joints of 60−80 degrees. Rubber bands were attached to all the fingernails. A small hook on which to hang the rubber bands was fastened to the plaster, creating a resting semiflexed position for the fingers between the training sessions. A night plate with the interphalangeal joints in extension was also made to protect the fingers and

keep them in full extension during sleep. The patients were instructed to flex their fingers passively with the uninjured hand, one finger at a time, and then keep the fingers in flexion and perform the place-and-hold. Then, the fingers were extended actively as far as the plaster allowed. During the first 4 postoperative weeks, the patient performed this exercise with 10 repetitions, 10 times a day, with a resting period of 1.5 hours between sessions. After 4 weeks, the plaster was removed and replaced by a wrist lacer protecting the wrist in a neutral position, and the patient added true active flexion of the fingers to the previous exercises, with 10 repetitions 10 times a day. Six weeks postsurgery, the wrist lacer was removed, and flexion and extension of the wrist were initiated and continued until 12 weeks postsurgery.

Statistical analysis

Nonparametric statistics were used, since the data were not normally distributed according to the Shapiro-Wilks test. Differences within the groups over time were analyzed with the Wilcoxon signed rank test. Differences in ROM, flexion contracture, grip strength, and key pinch measurements between the groups were assessed with the Mann-Whitney U test. Group comparisons of results from the DASH and ABILHAND questionnaires were also calculated with the Mann-Whitney U test. The chi-square test was used to assess the Strickland categories. A P value below .05 was considered statistically significant.

A power analysis was conducted prior to starting the study, as described in the previous article presenting the 1-year postoperative results.[6]

RESULTS

Patient demographics

Of the 64 patients initially randomized, 47 patients (17 women and 30 men) participated in this study (Fig. 1). For the long-term follow-up, we found that from the 64 included patients, 3 patients had died, 6 had tendon ruptures during the first postoperative year (3 in each group), 1 had an amputation of the finger after a subsequent injury, 1 patient in the active group had a tenolysis, 3 declined to participate, and 4 were lost to follow-up. Thus, 47 patients were available for examination at a minimum of 5 years after surgery (Fig. 1). Median age at surgery was 36 years (range, 17−69 years). Twenty-two patients had active mobilization and 25 had passive mobilization with place-and-hold. The median follow-up time after surgery was 79 months (range, 60−106 months). For patient demographics see Table 1.

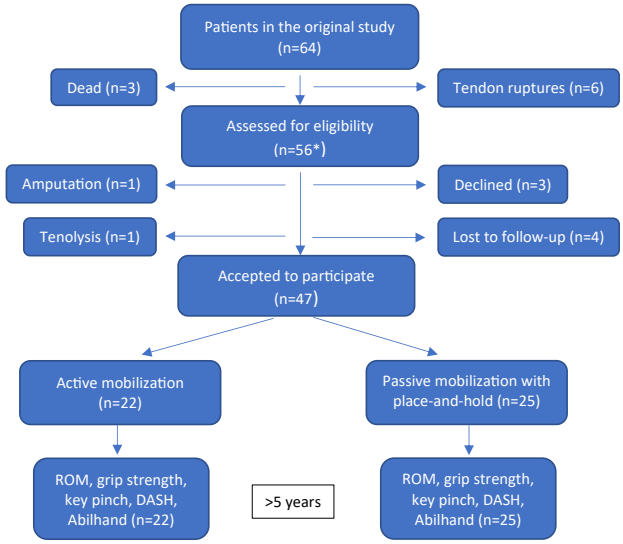

FIGURE 1: Consolidated Standards of Reporting Trials flow chart. *One of the patients with a tendon rupture died.

Range of motion

Between the 1-year and the 5-year minimum follow-up, the combined ROM in the PIP and DIP joints decreased significantly ($P < .05$), and the flexion contracture increased significantly ($P < .05$) in the active mobilization group. Range of motion and the flexion contracture did not change between the 1- and 5-year minimum follow-up in the passive mobilization group (Table 2). In addition, ROM was significantly better at the 5-year minimum follow-up in the passive mobilization group compared with the active mobilization group ($P < .05$) (Table 3). Furthermore, the active mobilization group showed a significantly larger flexion contracture at 1 year ($P < .05$). However, by a minimum of 5 years, there was no difference in flexion contracture between the groups (Table 3).

When ROM was categorized according to Strickland and Glogovac,[14] 15 % improved between 1 year after surgery and the long-term follow-up, whereas 19 % deteriorated. Significantly more patients had ROM categorized as excellent or good in the passive mobilization group (88 %) compared with the active group (64%) ($P < .05$) (Fig. 2).

Grip strength and key pinch

In both groups, grip strength decreased significantly ($P < .05$), whereas key pinch did not change from the 1- to 5-year minimum follow-up (Table 2). There were no significant differences in grip strength and key pinch between the active and the passive mobilization groups at the long-term follow-up (Table 3). Interestingly, the grip strength in the uninjured

TABLE 1. Demographics

		Active Mobilization n = 22	Passive Mobilization With Place-and-Hold n = 25
Age (y)	Median	37 (17–69)	36 (18–62)
Gender	Female	9	8
	Male	13	17
Occupation	Employed	14	22
	Student	5	2
	Unemployed	1	0
	Retired	2	1
Injury in dominant hand		7	13
Injured finger	Index	9	9
	Middle	2	7
	Ring	1	3
	Little	10	6
Concomitant injury	FDS	12	8
	Digital nerve	9	13
Zone	I	6	8
	II	16	17
Follow-up time median (mo)		81 (60–106)	75 (61–102)

Values within brackets indicate range.

TABLE 2. Within-Group Differences Over Time

Outcome Measurement	Mobilization Program	One Year Follow-Up	>5 y of Follow-Up	*P* value
ROM	Active	140 (47)	138 (53)	.04
	Passive with place-and-hold	148 (33)	155 (37)	.42
Flexion contracture	Active	20 (28)	26 (53)	<.01
	Passive with place-and-hold	4 (18)	4 (24)	.08
Grip strength	Active	37 (19)	32 (23)	<.01
	Passive with place-and-hold	42 (20)	37 (21)	<.01
Key pinch	Active	7.8 (2.2)	9.0 (4.5)	.11
	Passive with place-and-hold	9.6 (2.4)	9.3 (6.1)	.79
DASH score	Active	3.8 (13)	2.5 (9)	.64
	Passive with place-and-hold	4.2 (10)	3.3 (5)	<.05
ABILHAND score	Active	46 (1)	46 (0)	.72
	Passive with place-and-hold	46 (3)	46 (1)	.03

IQR, interquartile range. Values are given as median (IQR). *P* values have been calculated using the Wilcoxon signed rank test.

control hand also deteriorated significantly between 1- and 5-year minimum follow-up ($P < .05$).

DASH and ABILHAND

The changes in DASH and ABILHAND scores between 1 year and a minimum of 5 years were small in absolute numbers. DASH scores improved significantly in the passive mobilization group ($P < .05$), but not in the active mobilization group ($P > .05$) from 1-year to 5-year minimum follow-up. Likewise, ABILHAND scores improved significantly in the passive mobilization group ($P < .05$), but not in the

TABLE 3. Between-Group Differences

Outcome Measurement	Follow-Up (y)	Active	Passive With Place-and-Hold	*P* Value
ROM	1	140 (47)	148 (33)	.19
	>5	138 (53)	155 (37)	.03
Flexion contracture	1	20 (28)	4 (18)	.04
	>5	26 (53)	4 (24)	.07
Grip strength	1	37 (19)	42 (20)	.48
	>5	32 (23)	37 (21)	.38
Key pinch	1	7.9 (2.2)	9.6 (2.4)	.01
	>5	9.0 (4.5)	9.3 (2.6)	.65
DASH score	Baseline	0 (0)	0 (0.8)	.61
	1	4 (13)	4 (10)	.63
	>5	3 (9)	3 (8)	.35
ABILHAND score	1	46 (1)	46 (3)	.30
	>5	46 (0)	46 (1)	.92

IQR, interquartile range. Values are given as median (IQR). *P* values have been calculated using the Mann-Whitney test.

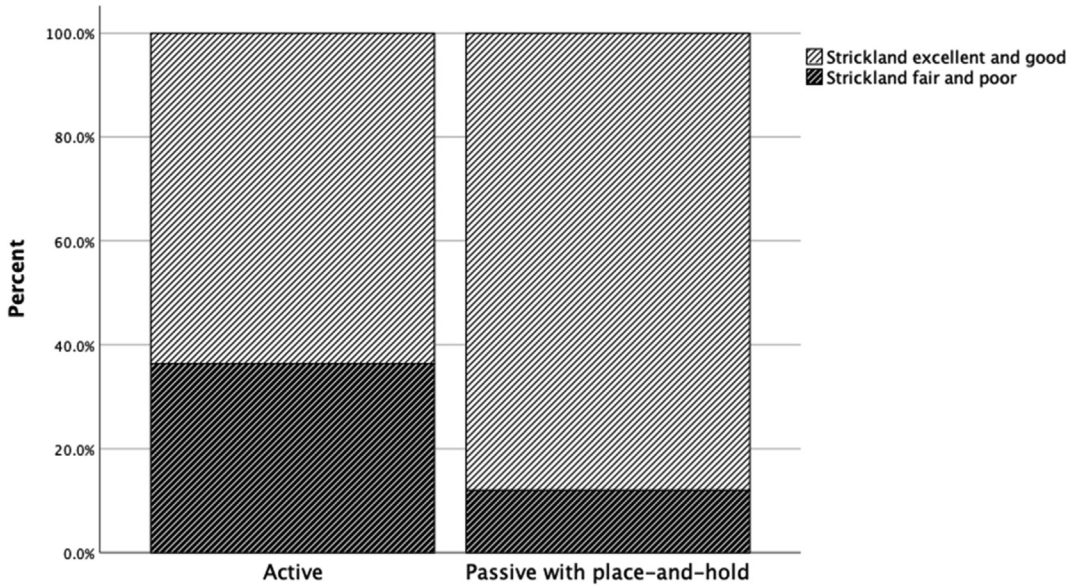

FIGURE 2: Strickland categories at the 5-year minimum follow-up. There is a significant difference between the groups, calculated with the chi-square test ($P < .05$).

active mobilization group ($P > .05$) (Table 2). However, the variability in data, as indicated by the interquartile range, was high, which could explain why there were no differences in DASH or ABILHAND scores between the two groups at the long-term follow-up (Table 3).

FDS injuries and zones I and II injuries

There was no significant difference in ROM, flexion contracture, grip strength, or key pinch when comparing fingers with a concomitant FDS injury with those who did not have an FDS injury (*P* values > .05). Likewise, there was no difference for any of the outcome parameters when comparing injuries in zone I with zone II (*P* values > .05).

DISCUSSION

In this RCT long-term follow-up, we found significantly better ROM in the group treated with passive mobilization in combination with place-and-hold

compared with active mobilization at a minimum follow-up of 5 years after surgery. The active mobilization group already had a significantly larger flexion contracture at 1 year, which was further increased at the long-term follow-up. In contrast, the flexion contracture did not change in the passive mobilization group.

With the introduction of new techniques in primary flexor tendon repair in recent decades, including stronger suture materials and suture techniques and venting of critical pulleys, various active rehabilitation regimes have been implemented.[13] Although there are theoretical advantages to more active rehabilitation regimes, both in terms of reducing adhesions and maximizing tendon excursion, evidence in their favor over passive mobilization and place-and-hold approaches is limited. Recent studies have shown a trend toward faster recovery at up to 3 months postsurgery for actively mobilized patients, but no differences at 12 months.[7,8] However, others have found significantly better ROM and grip strength among those treated with passive mobilization with place-and-hold compared with active mobilization at 6 months.[9]

In the current study, there were no significant differences between the two strategies concerning ROM, strength, and patient-reported outcomes 1 year after surgery. However, at 1 year, the flexion contracture was significantly less in the group treated with passive mobilization in combination with place-and-hold compared with active mobilization. Furthermore, from the 1-year to the 5-year minimum follow-up, ROM increased significantly, whereas the flexion contracture was unchanged in the group treated with passive mobilization. During the same period, ROM decreased in the active mobilization group, which could be due mainly to an increasing flexion contracture. A possible explanation for the smaller flexion contracture in the passive mobilization group at 1 year is that the fingers connected to rubber bands were subjected to small movements in the resting position during the first month after surgery. This contrasts with the active mobilization group who had a static splint against which the fingers rested between training sessions.

It was surprising that the flexion contracture in the active mobilization group increased from 1 year to the long-term follow-up, whereas it was stable in the passive mobilization group. Since we did not assess participants at intervals between the 1- and 5-year minimum follow-up, we cannot say if the flexion contracture increased gradually over time or rapidly after the follow-up at 1 year. However, we speculate that a flexion contracture, like the one seen in the active mobilization group at 1 year, may cause an imbalance between the flexor and the extensor system. When the PIP and DIP joints start to develop a flexion contracture, the patient can often compensate for this problem with hyperextension in the metacarpophalangeal joint. This, in turn, can result in increased tension in the flexor tendons and possibly a worsened flexion contracture in the affected finger over time.

We observed a significant decrease in grip strength in both groups between the 1-year and the 5-year minimum follow-up, with no difference between the groups. Interestingly, this decline also occurred in the uninjured, contralateral hand, suggesting a general deterioration of grip strength in adults over time.

Finally, in the current study, patient-reported DASH and ABILHAND scores improved in both groups from 1 to 5 years with a significant improvement in the passive mobilization group but not in the active mobilization group. However, the variability in data was high in both groups, as indicated by the interquartile range and the changes were small and thus likely not clinically relevant.

To our knowledge, there are no prior RCTs with a minimum of 5 years of follow-up. The minimum length of appropriate follow-up in hand surgery reports is debated. Tang et al[23] have suggested guidelines, including no less than 6 months generally for functional and nonfunctional outcomes. However, there is no established minimum follow-up length for flexor tendon surgery. A flexor tendon injury involves several layers of anatomical structures that are intended to glide in relation to one another. The healing and maturation of these structures take time, and the current study shows evidence of changes in ROM that take place between 1 year and at least 5 years after surgery. This finding highlights an important benefit of extended follow-up, beyond 1 year, of digital ROM after flexor tendon repair.

Our study has several limitations. The number of participants is relatively small. Although the 1-year follow-up had adequate power based on prestudy calculations, the 5-year follow-up fell slightly short due to participant loss. However, we believe this does not affect the validity of the comparisons, as they still show statistically significant differences.

We included injuries in both zones I and II, which might have affected the results. However, we excluded those cases where the distal injuries in zone I could not be treated with a four-stranded core suture. Furthermore, the statistical analysis did not show any difference between patients with injuries in zone I compared with those with injuries in zone II,

indicating that the inclusion of both zones likely did not alter the study results. As in most interventional studies, compliance was self-reported, and there is uncertainty regarding the true compliance rate of participants allocated to each rehabilitation program. However, this reflects what happens in clinical practice, where patients may receive even less supervision than they might in a clinical study. Nevertheless, participants had regular visits with an HT who assessed compliance at each visit, and no participant was considered noncompliant.

In addition, there were slightly more patients in the active group with a concomitant FDS injury, which could possibly affect the results. However, a comparison between patients with and without FDS injury failed to detect any significant difference for any of the outcome measurements.

Also, there was a higher rate of injuries in the little finger in the active group, which might have affected the results since little fingers are known to be challenging to rehabilitate compared with other fingers.

Larger RCTs with long-term follow-ups are needed to confirm the generalizability of our findings. Future studies should also assess patient-centered outcomes through qualitative investigations where patients who have gone through different rehabilitation protocols are interviewed about their experiences. This type of qualitative study can give additional information about how rehabilitation protocols can be designed for optimal compliance and outcomes.

In conclusion, the long-term follow-up of our RCT failed to detect any advantages of the increasingly popular early active mobilization therapy program over passive mobilization with place-and-hold after flexor tendon repair. On the contrary, ROM was significantly better in the passive mobilization group and the extension defect in the PIP and DIP joints worsened significantly over time in the active mobilization group.

CONFLICTS OF INTEREST

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